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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,234	01/13/2005	Satoshi Yonehara	10873.1574USWO	8752

7590 07/22/2009  
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EXAMINER
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ARIANI, KADE

ART UNIT	PAPER NUMBER
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1651

MAIL DATE	DELIVERY MODE
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07/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,234	<b>Applicant(s)</b> YONEHARA ET AL.	
	<b>Examiner</b> KADE ARIANI	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 11, 14 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>02/03/2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

The amendment filed on April 16, 2009, has been received and entered.

Claims 8, 10, 12, and 13 have been cancelled.

Claims 11, 14 and 15 are pending in this application and were examined on their merits.

Applicant's arguments with respect to claims 11, 14 and 15 have been fully considered but are moot in view of the new ground(s) of rejection.

***Claim Objection***

The objection of claim 11 is withdrawn.

Claim 15 is objected to because of the following informalities:

In claim 15 the phrase "glycated protein" lacks the proper grammatical article "a".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 8, and 10-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn due to applicant's amendments to the claims filed on 04/16/2009.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (EP 1 002 874 A2, May 24, 2000) and Glossary of class names of organic compounds (PAC, 1995, 67, 1307 Glossary of class names of organic compounds, pages 1351 and 1396), in view of Benezra et al. (US Patent No. 5,468,640), and further in view of Ishimaru et al. (Patent No. 6,127,138), is withdrawn due to Applicant's amendments to the claims file on 04/16/2009.

The rejection of claims 8, 10, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (EP 1 002 874 A2, Published June 24th, 2000) in view of Kaminagayoshi et al. (EP0158964 A2) and further in view of Armstrong (US

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Patent No. 4,102,810) and further in view of Johnson et al. (Blood, 1994, Vol.83, No.4, p.1117-1123), is withdrawn due to Applicant's amendments to the claims file on 04/16/2009.

Claims 11, 14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (EP 1 002 874 A2, May 24, 2000) and Glossary of class names of organic compounds (PAC, 1995, 67, 1307 Glossary of class names of organic compounds, pages 1351 and 1396) in view of Bauman et al. (US Patent No. 4,265,810) and Ledis et al. (US patent No. 5,731,206) and further in view of Kaminagayoshi et al. (EP0158964 A2) and Ishimaru et al. (Patent No. 6,127,138).

Claims 11, 14, and 15 are drawn to a method of measuring an amount of a glycated protein, the method comprising, treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound and a nitro compound, allowing a glycated portion of a glycated protein degradation product (obtained by the protease treatment) and a fructosyl amino acid oxidase to react with each other, and measuring the redox reaction, wherein the protease is a metalloproteinase, wherein the redox reaction is measured by determining an amount of hydrogen peroxide generated by the reaction of the glycated portion of the glycated protein degradation product and the fructosyl amino acid oxidase, wherein the amount of the hydrogen peroxide is determined by using an oxidase to reduce the generated hydrogen peroxide and oxidize a substrate that develops color by oxidation and measuring a degree of the color that the substrate has developed, wherein the degree

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of the color is measured by measuring an absorbance at a wavelength for detecting the substrate, and the degree of the color is measured by measuring an absorbance at a wavelength for detecting the substrate.

Komori et al. teach a method of measuring the amount of a glycated protein in a sample (Abstract, and page 2 0003 and 0004), pre-treating a sample with a nitro and a sulfonic acid compound (a tetrazolium compound) (page 2 0010, page 3 0017, page 6 0045, page 7 0061, and page 11). It must be noted that a sulfonic acid compound is an organic compound having  $\text{HS(=O)}_2\text{OH}$  formula, and a nitro compound have  $-\text{NO}_2$  group which may be attached to carbon, nitrogen, or oxygen (see PAC, Glossary of class names of organic compounds, pages 1369 and 1351). Therefore, the tetrazolium compound of Komori et al. could be considered as both a nitro and a sulfonic acid compound. Komori et al. teach the pretreated sample is treated with a protease (p.6 0050) (treating a sample containing the glycated protein with a protease in the presence of a sulfonic acid compound) (page 6 0045, page 7 0061). Komori et al. further teach to prepare a hemolyzed sample whole blood cells or blood cell fraction separated from whole blood may be hemolyzed using a surfactant (page 5 0043 and 0044). Komori et al. further teach a protease and degrading the glycated protein by a fructosyl amino oxidase to form hydrogen peroxide and measuring the quantity of hydrogen peroxide by measuring the degree of the color (0004, 0030, 0051) using a spectrophotometer (0059).

Komori et al. do not teach the sulfonic acid compound is 4-aminoazobenzene-4-sulfonic acid sodium, the nitro compound is 2, 4-dinitrophenol, and the protease is a

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metalloproteinase. However, Bauman et al. teach the sulfonic compound 4-aminoazobenzene-4-sulfonic acid sodium salt (column 4 lines 66-67).

Ledis et al. teach using nitro compound 2,4-dinitrophenol, in a reagent system for removing red blood cells (column 5 lines 46, and 65-66 and column 6 lines 60). Ledis et al. teach using sulfonic acid compounds, including benzene sulfonic acid in the reagent (column 6 line 45).

Kaminagayoshi et al. teach sodium salts of alkylbenzene sulfonic acids can be used as wetting agents in a method to determine an amount of hemoglobin, glucose, etc. in a sample. Kaminagayoshi et al. teach wetting agent serves to enable the body fluid in which the test piece is immersed to uniformly wet the test piece (page 8 last paragraph and page 9 1<sup>st</sup> paragraph line 1 and page 10 2<sup>nd</sup> paragraph).

Ishimaru et al. teach measuring an amount of a glycated protein in a sample by treating the glycated protein with Protease N (a metalloproteinase) (Abstract and Col.11, Table 2) in order to enhance the sensitivity of the detection (Col.5, Lines 59-63).

Therefore, in view of the above teachings, a person of ordinary skill in the art at the time the invention was made, would have been motivated to modify the method as taught by Komori et al. by using 4-aminoazobenzene-4-sulfonic acid sodium salt of Bauman et al. and 2,4-dinitrophenol as taught by Ledis et al. with a reasonable expectation of success in order to provide a method of measuring the amount of a glycated protein, because Ledis et al. teach using the nitro compound 2,4-dinitrophenol and benzene sulfonic acid in a reagent system for removing red blood cells, and

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because Kaminagayoshi et al. teach using alkylbenzene sulfonic acids as wetting agents in a method to determine an amount of hemoglobin.

Moreover, a person of ordinary skill in the art at the time the invention was made could have been motivated to substitute the protease in the method of Komori et al. with the protease as taught by Ishimaru et al. with a reasonable expectation of success in obtaining a glycated protein degradation product, because Ishimaru et al. teach treating the glycated protein with a metalloproteinase to measure an amount of a glycated protein in a sample. The motivation as taught by Ishimaru et al. would be to enhance the sensitivity of the detection.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination yielded nothing more than predictable results to one of ordinary skill in the art. KSR, 550 U.S. at \_\_\_\_, 82 USPQ2d at 1395; Sakraida v. AG Pro, Inc., 425 U.S. 273, 282, 189 USPQ 449, 453 (1976); Anderson 's-Black Rock, Inc. v. Pavement Salvage Co., 396 U.S. 57, 62-63, 163 USPQ 673, 675 (1969); Great Atlantic & P. Tea Co. v. Supermarket Equipment Corp., 340 U.S. 147, 152, 87 USPQ 303, 306 (1950).

### ***Conclusion***

No claims are allowed.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kade Ariani whose telephone number is (571) 272-6083. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

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Kade Ariani  
Examiner  
Art Unit 1651

/Leon B Lankford/  
Primary Examiner, Art Unit 1651